



PATENT
Attorney Docket No. 220551

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Roberts et al.

Group Art Unit: 1614

Application No. 10/644,530

Examiner: Unassigned

Filed: August 20, 2003

For: METHOD FOR INCREASING THE
BIOAVAILABILITY OF
GLYCOPYRROLATE

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Pursuant to 37 CFR 1.97 and 1.98, the references listed on the enclosed Form PTO-1449 and/or Substitute Form PTO-1449 ("Form 1449") are submitted for consideration by the Examiner in the examination of the above-identified patent application.

The full consideration of the references in their entirety by the Examiner is respectfully requested and encouraged. Also, it is respectfully requested that the references be entered into the record of the present application and that the Examiner place his or her initials in the appropriate area on the enclosed Form 1449, thereby indicating the Examiner's consideration of each of the references.

The submission of the references listed on the Form 1449 is for the purpose of providing a complete record and is not a concession that the references listed thereon are prior art to the invention claimed in the patent application. The right is expressly reserved to establish an invention date earlier than the above-identified filing date in order to remove any reference submitted herewith as prior art should it be deemed appropriate to do so.

Further, the submission of the references is not to be taken as a concession that any reference represents art that is relevant or analogous to the claimed invention. Accordingly, the right to argue that any reference is not properly within the scope of prior art relevant to an examination of the claims in the above-identified application is also expressly reserved.

The Information Disclosure Statement is being filed:

- ☒ **within** any one of the following time periods: (a) within three months of the filing date of a national application other than a continued prosecution application under 37 CFR 1.53(d); (b) within three months of the date of entry of the national stage as

set forth in 37 CFR 1.491 of an international application; (c) before the mailing date of a first Office Action on the merits; or (d) before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

- ☐ **after** (a), (b), (c) or (d) above, but before the mailing date of a final action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and includes *one* of:

☐ the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below).

or

☐ the fee of \$180 set forth in 37 CFR 1.17(p) (see "Fees" below).

- ☐ **after** the mailing date of a final action under 37 CFR 1.113 or a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and on or before payment of the issue fee, and includes the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below), and the fee of \$180 as set forth in 37 CFR 1.17(p) (see "Fees" below).

- ☐ **after** the mailing date of a Notice of Allowance under 37 CFR 1.311, and on or before payment of the issue fee, and **within** thirty days of receiving each item of information contained in the Information Disclosure Statement, and includes the Statement under 37 CFR 1.704(d) (see "Statement under 37 CFR 1.704(d)" below), and the fee of \$180 as set forth in 37 CFR 1.17(p) (see "Fees" below).

NOTE: This is for original applications except applications for a design patent, filed on or after May 29, 2000, wherein a paper containing only an Information Disclosure Statement in compliance with 37 CFR 1.97 and 1.98 is being filed.

Copies of the References

- ☒ Copies of all of the references listed on the enclosed Form 1449 are enclosed herewith.
- ☐ This patent application was filed after June 30, 2003. Accordingly, copies of U.S. patents and patent applications that are listed on the accompanying Form 1449 are not enclosed herewith (see Official Gazette Notice of August 5, 2003). Copies of other references identified on the accompanying Form 1449 are enclosed herewith.
- ☐ Attached to each reference not in the English language is a concise explanation of the relevance pursuant to 37 CFR 1.98(a)(3). An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of the relevance pursuant to 37 CFR 1.98(a)(3).
- ☐ A copy of the foreign search report is enclosed herewith.

- ☐ The references listed on the enclosed Form 1449 were previously identified in the parent application(s) of the present application, and copies of the references were furnished at that time. Accordingly, additional copies of the references are not submitted herewith, so as not to burden the file with duplicate copies of references. The Examiner is respectfully requested to carefully review the references in accordance with the requirements set out in the Manual of Patent Examining Procedure. In accordance with 37 CFR 1.98(d), the details of the parent application(s) relied upon for an earlier filing date under 35 USC 120 in which copies of the references were previously furnished are set out below:

U.S. APPLICATIONS		Status (<i>check one</i>)		
U.S. APPLICATIONS	U.S. FILING DATE	PATENTED	PENDING	ABANDONED
1.				
2.				
3.				

Statement under 37 CFR 1.97(e)

- ☐ The **undersigned** hereby states that each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.
- ☐ The **undersigned** hereby states that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the Information Disclosure Statement.

Statement under 37 CFR 1.704(d)

- ☐ The **undersigned** hereby states that each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and that this communication was not received by any individual designated in 37 CFR 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

Fees

- ☒ No fee is owed by the applicant(s).
☐ The **IDS Fee of \$180** under 37 CFR 1.17(p) is enclosed herewith.

In re Appln. of Roberts et al.
Application No. 10/644,530

Method of Payment of Fees

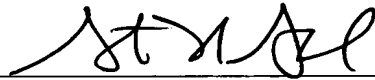
- ☐ Attached is a check in the amount of \$.
☐ Charge Deposit Account No. 12-1216 in the amount of \$. (A duplicate copy of this communication is enclosed for that purpose.)

Authorization to Charge Additional Fees

- ☒ If any additional fees are owed in connection with this communication, please charge Deposit Account No. 12-1216. (A duplicate copy of this communication is enclosed for that purpose.)

Instructions as to Overpayment

- ☒ Credit Account No. 12-1216.
☐ Refund



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Date: March 25, 2004

Please type a plus sign (+) inside this box →



Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)			Complete if Known		
			Application Number	10/644,530	
			Filing Date	August 20, 2003	
			First Named Inventor	ROBERTS, Alan	
			Group Art Unit	1614	
			Examiner Name	Unassigned	
Sheet	1	of	2	Attorney Docket Number	220551

U.S. PATENT DOCUMENTS						
Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date If Appropriate
		Application or Patent Number	Kind Code			
	AA	6,407,128		Scaife et al.	Jun. 18, 2002	
	AB	6,455,557		Pellegrini et al.	Sep. 24, 2002	

FOREIGN PATENT DOCUMENTS								
Examiner Initials	Doc. No.	Foreign Patent Document			Name of Patentee or Applicant	Date of Publication	Translation	
		Office	Application or Patent Number	Kind Code			Yes	No**
	AC	WO	01/08681	A1	First Horizon Pharmaceutical Corp.	Feb. 8, 2001		

OTHER - NON PATENT LITERATURE DOCUMENTS						
Examiner Initials	Doc. No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Translation			
			Yes	No**		
	AD	Ali-Melkkila et al, "Glycopyrrolate: pharmacokinetics and some pharmacodynamic findings," <i>Acta Anaesthesiol. Scand.</i> , 33: 513-517 (1989).				
	AE	Ali-Melkkila et al., "Pharmacokinetics and related pharmacodynamics of anticholinergic drugs," <i>Acta Anesthesiol. Scand.</i> , 37: 633-642 (1993).				
	AF	Chen, "Troglitazone: An antidiabetic agent," <i>Am J. of Health-Syst. Pharm.</i> , 55: 905-925 (1998).				
	AG	Evans, "Influence of Dietary Components on the Gastrointestinal Metabolism and Transport of Drugs," <i>Therapeutic Drug Monitoring</i> , 22: 131-136 (2000).				
	AH	Greene et al., "Clinical Pharmacokinetics of Nefazodone," <i>Clin. Pharmacokinet.</i> , 33(4): 260-275 (1997).				
	AI	Gillen et al., "Problems related to acid rebound and tachyphylaxis," <i>Best Pract. & Res. Clin. Gastroenterology</i> , 15(3): 487-495 (2001).				
	AJ	Kirk, "Significant Drug-Nutrient Interactions," <i>Amer. Fam. Phys.</i> , 51(5): 1175-1182 (1995).				
	AK	Loi et al., "Clinical Pharmacokinetics of Troglitazone," <i>Clin. Pharmacokinet.</i> , 37(2):91-104 (1999).				
	AL	Martinez et al., "A Mechanistic Approach to Understanding the Factors Affecting Drug Absorption: A Review of Fundamentals," <i>J. Clin. Pharmacol.</i> , 42: 620-643 (2002).				
	AM	Pelkonen et al., "In vitro prediction of gastrointestinal absorption and bioavailability: and experts' meeting report," <i>Eur. J. Clin. Pharmacol.</i> , 57: 621-629 (2001).				
	AN	Rautakorpi et al., "Pharmacokinetics and Oral Bioavailability of Glycopyrrolate in Children," <i>Pharmacology & Toxicology</i> , 83: 132-134 (1998).				

Examiner Signature		Date Considered	
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* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

+ An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3).

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(Use as many sheets as necessary)

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Sheet

2

of

2

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